IMPACT Instrumentation Inc.

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FEB 16 2012

510(k) Summary K111473

This 510(k) summary consists of a table with the information required in the 510(k) Summary Checklist from the FDA Guidance document.

Description of Required Information	Information
Owner's Name	Leslie H. Sherman (President)
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Contact Person	Susan McNevin Ph.D., CQE/CQA Quality Engineer, Impact Instrumentation, Inc.
Date this Summary was prepared	December 28, 2010
Trade name of device	Uni-Vent® Model 731 Series Portable Critical Care Ventilators Versions: EMV+® EMV+®- MRI version Eagle II™ Eagle II™- MRI version AEV® AEV®- MRI version
Common name	ventilator
Classification name	Continuous Ventilator (21 CFR 868.5895, Product Codes CBK, DQA)
Legally marketed device – Equivalence Claim	Uni-Vent® Model 731 Series Portable Critical Care Ventilators (K103318).
Description of the device	The below is taken from the Operation Manual: • The Model 731 Ventilators are a small, extremely durable, full-featured portable mechanical ventilators

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	designed to operate in hospitals or austere and under-resourced environments. • The unit is a volume and pressure targeted, time or flow cycled ventilator designed to use either oxygen (O_2) from a 55 psig source or fresh air using its internal compressor to deliver a positive pressure breath. • The unit contains a pulse oximeter which is intended for continuous noninvasive monitoring of arterial hemoglobin (SpO_2) and pulse rate (measured by the SpO_2 sensor). • The unit contains various controls and indicators that are placed to facilitate ease of use and visibility in all operating environments. A liquid crystal display (LCD) provides continuous display of control settings, operating conditions, power, and alarm status information. • The unit uses a comprehensive suite of alarms to alert the operator and guide their actions to resolve the alarm condition and assure patient safety. At the onset of an alarm, the screen displays the alarm name and then a series of context-sensitive help messages. These messages serve to guide the operator by presenting suggestions as to the cause and resolution of a particular alarm. When multiple alarms occur they are prioritized and displayed based on the risk to the patient. • The unit offers a range of modes using both pressure and volume targeting that can be selected to optimally manage the patient. Assist/Control (AC): patient receives either controlled or assisted breaths. When the patient triggers an assisted breath they receive a breath based on either the volume or pressure target. Synchronized Intermittent Mandatory Ventilation (SIMV): patient receives controlled breaths based on the set breathing rate. Spontaneous breaths can be either unsupported demand flow or supported using Pressure Support. (This mode is not available in the AEV® unit.) Continuous Positive Airway Pressure (CPAP): patient receives constant positive airway pressure while breathing spontaneously. Spontaneous breaths can

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	be either demand flow or supported using Pressure Support. • The unit contains a built-in back up ventilator mode that is designed to provide a limited degree of operation should certain types of failures occur to the primary operating system. • The unit can be used in environments where chemical and/or biological toxins are present. To do this safely, all gas delivered to the patient comes from either a pressurized medical-grade O_2 source and/or filtered ambient air entrained through the FRESH GAS/EMERGENCY AIR INTAKE. Operators can chose between a bacterial/viral filter and a chemical/biological filter based on the direction of the Medical Control Officer. To prevent the patient from breathing contaminated ambient air in the event of a ventilator failure, the unit contains an internal anti-asphyxia valve that allows the patient to inspire gas through the external filter. • The unit continuously monitors environmental conditions (temperature and ambient pressure) and when extreme environments are detected the operator is alerted by a low priority alarm which defines the operating condition and prompts the actions of the operator. • The unit uses a rechargeable lithium-ion battery which offers a wide temperature operating range, does not exhibit "memory" characteristics (reduced capacity) or vent hydrogen gas. • The unit can use O_2 from low flow sources, O_2 flow meters and O_2 concentrators, to provide supplemental O_2 to patients. To do this, O_2 is entrained through the Fresh Gas/Emergency Air Intake when the unit's internal compressor cycles to deliver a breath. • The testing in MRI environment was done with a 3.0 T Siemens Trio scanner, which has a magnetic field of 0.2 T (500 gauss) at a distance of slightly more than 1 meter (~3.3 feet) from the bore entrance. There was no effect on either the ventilator functionality or the MRI performance at a distance of 2 meters.
Intended Use of Device	The Intended Use is taken from the Operation Manual: The devices in the Model 731 Ventilator Series are indicated for use in the management of infant through adult patients weighing ≥5 kg with acute or chronic respiratory failure or

Description of Required Information	Information
	during resuscitation by providing continuous positive-pressure ventilation. They are appropriate for use in hospitals, outside the hospital, during transport and in austere environments where they may be exposed to rain, dust, rough handling and extremes in temperature and humidity. With an appropriate third-party filter in place, they may be operated in environments where chemical and/or biological toxins are present (see External Filter Use). When marked with an "MRI conditional" label, they are suitable for use in an MRI environment with appropriate precautions, as defined in the Operation Manual. They are **not** intended to operate in explosive environments. The Model 731 Ventilators are intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation and by first responders under the direction of skilled medical care providers. The EMV+® and Eagle II™ (with and without MRI label) have a full range of ventilation modes (AC, SIMV, CPAP with PS and NPPV-PPV). The AEV® (with and without MRI label) provides specific modes consistent with pre-hospital care provider's operating procedures (AC, CPAP with PS and PPV). The only difference in this Intended Use from the Predicate is the addition of operation in an MRI environment.
Comparison Technological Characteristics to Predicate	There is no change in either the software or the hardware. The only difference is external conditional MRI label and Operation Manual.

Description of Required Information	Information
Non-Clinical Performance data	• It was demonstrated that there was no effect on either the ventilator functionality or the MRI performance at a distance of 2 meters from a 3.0 T Siemens Trio scanner, which has a magnetic field of 0.2 T (500 gauss) at a distance of slightly more than 1 meter. o This test meets the acceptance criteria defined in FDA Draft Guidance "A Primer on Medical Device Interactions with Magnetic Resonance Imaging systems" o Location of testing: passed o Imaging sequence: passed o Effect on Medical Device: passed o Generation of Artifact/Noise: passed • The longer breathing circuit required for MRI operation passed testing to ASTM F1100 requirements. o Section 5.3 Waveform Performance: passed o Section 5.4 Volume Performance: passed
Clinical Performance	N/A. No clinical performance data is being submitted.
Safe and Effective as Predicate	The testing demonstrates that these devices are as safe and effective and performs as well as or better than the Predicate device (K103318).
Other Information requested by FDA	Impact Instrumentation, Inc. will provide the FDA with any additional required information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Susan McNiven
Quality Engineer
Impact Instrumentation, Inc.
27 Fairfield Place
West Caldwell, New Jersey 07006

FEB 16 2012

Re: K111473
Trade/Device Name: Uni-Vent® 731 Series Model Portable Critical Care Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 2, 2011
Received: February 1, 2012

Dear Ms. McNevin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111473

Device Name: Uni-Vent® 731 Series Model Portable Critical Care Ventilator

Indications For Use: (the text in red shows Additions to Predicate device)

INTENDED USE

The devices in the Model 731 Ventilator Series are indicated for use in the management of infant through adult patients weighing ≥5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. They are appropriate for use in hospitals, outside the hospital, during transport and in austere environments where they may be exposed to rain, dust, rough handling and extremes in temperature and humidity. With an appropriate third-party filter in place, they may be operated in environments where chemical and/or biological toxins are present (see External Filter Use). When marked with an "MRI conditional" label, they are suitable for use in an MRI environment with appropriate precautions, as defined in the Operation Manual. The Model 731 Ventilators are intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation and by first responders under the direction of skilled medical care providers. The EMV+® and Eagle II™ (with and without MRI label) have a full range of ventilation modes (AC, SIMV, CPAP with PS and NPPV-PPV). The AEV® (with and without MRI label) has a more limited range of ventilation modes for less sophisticated operators (AC, CPAP with PS and PPV).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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